

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

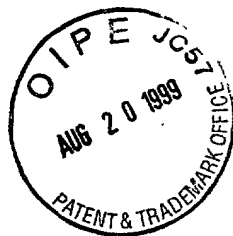
In re Application of:

CARL E. HANSON

Serial No.: 08/903,677

Filed: July 31, 1997

For: METHOD OF TREATING ANGINA



Box AF

Group Art Unit: 3738

Examiner: Dinh Nguyen

#14

APPEAL BRIEF

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This Appeal Brief is submitted in accordance with the terms of 35 U.S.C. § 134 and 37 C.F.R. § 1.192 in response to the final Office Action mailed March 15, 1999. Appellants furnish the Appeal Brief in triplicate. Enclosed is a check for \$155.00 to cover the processing fee set forth in 37 C.F.R. § 1.17(c).

I. Real Party In Interest

Carl E. Hanson of Lanark Village, Florida is the real party in interest.

II. Related Appeals and Interferences

Appellants are unaware of any related appeals or interferences.

III. Status of Claims

Claims 1-17 are pending in the application and are the subject of this appeal.

IV. Status of Amendments

No amendments have been filed after the final rejection.

V. Summary of the Invention

Doctors regularly prescribe nitroglycerin to patients who suffer from chest pain such as angina pectoris. The nitroglycerin is commonly administered in the form of very small tablets that are approximately 1/8 inch in diameter. These tablets are difficult for the patient to handle: they can be easily dropped, and often more than one tablet comes out of the bottle during dispensing. The small tablet size also makes it hard for the patient to return unneeded tablets to the bottle, particularly when moisture is present on the patient's hand. When taking nitroglycerin, the patients put the tablet under their tongue and wait for about two to four minutes for the tablet to dissolve. Sometimes the patient cannot easily ascertain if the medicine has been properly ingested. A patient waits for approximately five minutes for the chest pain to subside.

The present invention provides another alternative to chest-pain sufferers. In accordance with the present invention, a person takes in lime juice after noticing the onset of cardiac chest pain. The inventor discovered that by taking lime juice shortly after noticing the chest pain from the heart, that the pain immediately subsided. This result was only noticed for lime juice. It did not occur when the applicant consumed other tropical juices such as orange juice.

This method of alleviating cardiac chest pain is advantageous in that it is easy for the patient to determine if the medicine has been properly ingested. Lime juice has a very noticeable taste that disappears after it leaves the mouth. Since it can be regularly stored in the refrigerator or freezer, lime juice can be quickly located by the patient, particularly at nighttime when the refrigerator light plays a helpful role. The need to immediately locate the medicine is very important because time may be of the essence when experiencing cardiac chest pain. A patient does not have to wait two-to-four minutes for a tablet to dissolve, and there is no concern for dropping tablets on the floor. Lime juice also costs much less than nitroglycerin and, because it is a naturally occurring product it will generally not present serious side effects.

VI. Issues Presented

1. The patent application describes a method of preventing the recurrence of cardiac chest pain by taking lime juice shortly after experiencing the pain. Three actual examples are set forth in the patent application which show how the chest pain subsided almost immediately after lime juice was taken. Did the applicant describe the invention in such a way that any person

skilled in the art can make and use the invention, as required by the 35 U.S.C. § 112, first paragraph?

2. The claims use the terminology "effective amount" and "active ingredients" to describe the invention. The term "effective amount" is defined on page 4, line 18, as being "an amount sufficient to have a beneficial effect on the heart after noticing the chest pain." The term "active ingredients" is recognized by persons skilled in the art as being the ingredients that are actually responsible for causing or initiating the desired change. Does the use of these terms render the claims indefinite under 35 U.S.C. § 112, second paragraph, despite their explicit and understood meanings?

3. The claimed invention involves taking lime juice into the body shortly after experiencing chest pain. The documents cited by the Examiner, namely, Singh et al., Langtry et al., Riemersma et al., or Dapcich-Miura et al., merely disclose the use of vitamins, orange juice, etc. in connection with cardiac conditions. Can these documents be anticipatory under 35 U.S.C. § 102?

4. The claimed invention involves taking lime juice into the body shortly after experiencing chest pain. The documents cited by the Examiner, namely, Singh et al., Langtry et al., Riemersma et al., or Dapcich-Miura et al., teach the use of vitamins, orange juice, etc. in connection with cardiac conditions. Can these documents render the present invention obvious to a person of ordinary skill under 35 U.S.C. § 103?

VII. Grouping of Claims

The claims will stand or fall together.

VIII. Argument

Issue 1

In making the enablement rejection, the Examiner has taken the position that the applicant "has given no proof that the method as claimed would prevent 'chest pain'". Applicant strongly

disagrees with this position. The specification is replete with descriptions of how chest pain is alleviated by taking lime juice into the body. Indeed, there are a number of working examples where the applicant personally demonstrated this effect.

After performing numerous experiments, the applicant was so comfortable with the results that he replaced his nitroglycerin prescription with the use of lime juice and still uses it today. Considering the risks that are entailed by not taking a prescription medicine for a heart condition, the results the applicant experienced were quite astonishing. Applicant does not simply attest that he has received "beneficial effects" from drinking a "large quantity" of lime juice. The Examiner's reference to a placebo effect, and that the result may have stemmed from vitamin C, are purely speculative. The Examiner's remarks concerning psychological effects are not supported by the record, particularly when the relief experienced is immediate and is encountered by taking less than a teaspoon of frozen concentrated lime aid. Applicant's disclosed utility must be accepted as being accurate when the record is devoid of any authority in variance to that utility. *In re Bundy*, 209 USPQ 48, 51 (CCPA 1981) ("The PTO must had adequate support for its challenge to the applicant's statements as to utility. Only then does the burden shift to appellant to provide rebuttal evidence."); *In re Gazave*, 154 USPQ 92 (CCPA 1967) ("[a]ppellant's assertions of usefulness in his specification appear to us to be believable on their face and straightforward, at least in the absence of reason or authority in variance.").

Presently, the Examiner contends that "[a]pplicant's condition as described in the specification, may be due to the wide belief that vitamin C, and related sources such as orange juice, are good for the body." No evidence, however, is presented to support this position. Applicant does not assert in any event, that vitamin C is the critical component to alleviating chest pain. Indeed, applicant does not witness beneficial effects when taking other vitamin C containing products. Applicant notices the improved results when using lime juice and has been consistently and successfully using the product for his cardiac condition at least since the filing of this application.

Because the present application describes in clear terms how chest pain can be alleviated through use of lime juice, and because there is no cogent evidence of record which sufficiently contradicts this representation, it must be accepted as being accurate.

Issue 2

Claims 1-17 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the reasons given in regard to lack of enablement for the terms "active ingredients" and "effective amount". The Examiner has not, however, explained how these terms can render the claim indefinite. It is incumbent upon the Examiner to give reasons that explain why the *claim is imprecise*. As the Board is aware, the focus of the inquiry is on the claim language. It is not proper for the Examiner to refer to an "absence of proof" in making such a rejection. *In re Ehrreich*, 200 USPQ 504, 507-08 (CCPA 1979) ("The second paragraph of Section 112 pertains *only* to claims....Agreement, or lack thereof, between the claims and the specification is properly considered only with respect to the first paragraph of § 112; it is irrelevant to compliance with the second paragraph of that section.").

Issue 3

None of the documents that have been cited by the Examiner disclose the intake of lime juice by a person shortly after experiencing chest pain. Indeed, none of the documents even mention lime juice. Without such a disclosure, the claims clearly are not anticipated under the terms of 35 U.S.C. § 102(b).

Issue 4

In regard to the obviousness rejection, none of the documents teaches or suggests using lime juice to alleviate chest pain associated with a cardiac condition.

Singh discloses a placebo-controlled trial where a cocktail of vitamin A, vitamin C, vitamin E, and beta carotene are given to patients who are suspected to have acute myocardial infarction. This document does not suggest that lime juice can be taken to counter the effects of angina pectoris. Lacking such a teaching or suggestion, this reference clearly would not have led a person of ordinary skill to the present invention.

Langtry et al. discloses how a nisoldipine core-coat controls systems of angina and approves exercised-induced signs of ischaemia in patients with stable angina. This document does not teach or suggest the beneficial effects of taking lime juice after experiencing cardiac chest pain. To the extent that the Examiner believes that such a connection would be made based on a

relation to vitamin C, this reference recommends against the use of grapefruit juice when taking nisoldipine therapy. If anything, this document teaches away from applicant's invention.

Reimersma et al. examines the risk between angina pectoris and plasma concentrations of vitamins A, C, and E and carotene. Nowhere does this document teach or suggest taking lime juice into the body to alleviate cardiac chest pain. The document merely discusses the relationship between concentrations of these vitamins in plasma to persons who exhibit angina.

Dapcich-Miura et al. also would not have rendered applicant's invention obvious. This document describes how an experimentee, namely Mr. A, could be induced into increasing adherence to a complex medical regimen. Using certain intervention, Mr. A began walking, drinking orange juice, and taking all of his prescribed medication. The document merely describes a regimen that can be employed to increase medication use to alleviate angina pain. Although the reference mentions another fruit juice, namely orange juice, it in no way suggests the use of lime juice to immediately alleviate chest pain associated with a cardiac condition. Indeed the applicant has drank orange juice after experiencing an angina attack but detected no relief from such a product. Lacking any suggestion of using lime juice or the beneficial effects that can be immediately achieved through such use by a person with angina, this document clearly does not teach or suggest the present invention.

In view of the failure of all of the references cited by the Examiner to teach or suggest the use of lime juice shortly after experiencing cardiac chest pain, these documents surely would not have made applicant's invention obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.

IX. Conclusion

A person of ordinary skill will surely be able to practice the present invention after a reading of the present specification. There is nothing in the record which indicates otherwise. It is not a difficult task, nor is it one that would require undue experimentation, for a person to take lime juice shortly after noticing cardiac chest pain. There is also nothing in the record to support the proposition that the terms "effective amount" and "active ingredients" would render the claims indefinite. And none of the documents relied upon to make the prior art rejection even remotely teach the basic steps of the invention.

For these reasons, appellants respectfully submit that the Examiner has erred in continuing to reject this application under 35 U.S.C. § § 112, 102, and 103. Please reverse the Examiner on all counts.

Dated this 16th day of August, 1999.

Respectfully submitted,



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/Appeal Brief

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, DC 20231, on the date noted below.


Karl G. Hanson

Dated: August 16, 1999

APPENDIX

1. A method of preventing the reoccurrence of chest pain associated with the heart, which method comprises:

- (a) noticing a pain in the chest; and then shortly thereafter
- (b) taking lime juice into the body to alleviate the chest pain.

2. The method of claim 1, wherein the chest pain is angina pectoris.

3. The method of claim 1, wherein the lime juice enters the body by consuming it orally.

4. The method of claim 2, wherein the lime juice is consumed in concentrated form by taking at least one half teaspoon of frozen concentrated lime juice or limeade.

5. The method of claim 1, further comprising:
preventing the reoccurrence of chest pain by taking lime juice into the body daily.

6. The method of claim 5, wherein at least one cup of lime juice is consumed orally daily.

7. The method of claim 6, wherein 2 to 5 cups are consumed daily.

8. The method of claim 6, wherein 2 to 3 cups are consumed daily.

9. A method of treating angina pectoris, which method comprises:

- (a) noticing the onset of an angina attack; and then shortly thereafter
- (b) taking an effective amount of lime juice into the body.

10. The method of claim 9, wherein the lime juice is taken orally.

11. The method of claim 10, wherein the lime juice is essentially pure lime juice.

12. The method of claim 10, wherein the lime juice is frozen concentrate for limeade.
13. The method of claim 10, wherein the lime juice is limeade.
14. The method of claim 1, wherein the lime juice is administered in concentrated form.
15. The method of claim 1, wherein the lime juice is administered in the form of its active ingredients.
16. The method of claim 9, wherein the lime juice is administered in concentrated form.
17. The method of claim 9, wherein the lime juice is administered in the form of its active ingredients.